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08/461,402	06/05/1995	ANDREW H. CRAGG	94-P0273US02	6448

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EXAMINER	
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ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/461,402	CRAGG ET AL.	
	Examiner	Art Unit	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *96-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *96-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 96 is objected to because of the following informalities: in the last line of the 5th indented section, "bifurcate" should read "bifurcated". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 96-106** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 96, 104, and 106 all include that the cross-sectional area (CSA) of the distal orifice of the proximal stent when expanded is sufficiently less than that of the proximal end of the distal stent so as to at least partially secure together the proximal and distal stents. Although the instant specification includes that the proximal end of the distal stent fits within the distal orifice of the proximal stent, it does not disclose the CSA of either portion, either in dimensions or in relation to each other. Note that this limitation also appears again in claim 98.

4. Additionally, claims 96, 104, and 106 all claim "at least two transversely placed tapering portions". It appears that the specification does not have support for more than two of such portions and therefore "at least two" tapering portions is new matter. Claim 106 includes "at

least two distal orifices" on the proximal stent. This is new matter because the specification only supports two distal orifices on the proximal stent, not "at least two".

5. Claim 100 includes “the composite radiographic image" and “the rotational orientation” which both lack antecedent basis. In line 3 of the claim, it is unclear which stent the limitation "the stent" refers to (proximal or distal stent?). Also, in line 6 of claim 100, "the body lumen” should read “the bifurcated lumen”

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **Claims 97, 98, and 101-103** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 97: claim 96 includes a proximal stent having at least two tapering portions that extend from an intermediate portion to a distal end of the proximal stent. However, claim 97 then goes on to claim a first intermediate and a second intermediate portion. It is unclear from the wording if the first and second intermediate portions are in addition to the intermediate portion of claim 96 or if the intermediate portion of claim 96 comprises first and second intermediate portions. Furthermore, the "a relatively short inclined extension" appears to be one of the "two transversely placed tapering portions" of claim 96 instead of an additional element as it is currently claimed. In other words, claim 97 includes several limitations to portions that have already been claimed in 96 but the claims have not been worded in a manner that makes this clear. Appropriate correction is required.

9. Claim 98: similar to claim 97, claim 98 includes several limitations that appear to already have been claimed in 96 without making it clear that the claim is further defining these already

claimed elements instead of claiming additional elements. Claim 98 includes that the distal end of the proximal stent has first and second distal portions, each with a distal orifice. However, claim 96 already includes "at least one distal orifice at the distal end of at least one of the tapering portions". The distal orifice of the first and second distal portions appears to be the same as the "at least one distal orifice" of the tapering portions of claim 96. If this is applicant's intent, the claim needs to be reworded to indicate that the “at least one distal orifice” of claim 96 comprises a first distal orifice on the first distal portion and a second distal orifice on the second distal portion. Furthermore, the first and second distal portions appear to be the "at least one tapering portion" of claim 96 but this is unclear in the claim.

10. Claim 101: the wording of this claim regarding "an assembly of proximal and distal stents" is unclear since the proximal and distal stents do not reference earlier claimed stents (no “the” or “said”). It is suggested that the claim be changed to ".... claim 96, wherein an assembly of the proximal and distal stents are configured...". The claim must include "the” in front of “proximal” in order to clarify that the stents of claim 101 refer back to those of 96 and are not additional proximal and distal stents.

11. Claims 102 and 103: "the" should be inserted between "the assembly of" and "proximal"

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. **Claims 96-99 and 101-103** are rejected under 35 U.S.C. 102(e) as being anticipated by Martin (US 5,575,817). Martin discloses an apparatus for reinforcing a bifurcated lumen comprising a proximal stent (1) having a proximal and distal end, the proximal stent further having a proximal orifice at the proximal end to be located in and when expanded to be supported by a vascular vessel, at least one distal stent (2) having a proximal and distal end. The proximal stent has two transversely placed tapering portions that extend from an intermediate portion to the distal end of the proximal stent to reinforce the bifurcated lumen. In particular, note that the sections near reference numbers 1 and 5 in fig. 4 are tapered. These sections extend to the distal end of the proximal stent. The proximal stent has a distal orifice at the distal end of at least one of the tapering portions which, when expanded, serves to receive the proximal end of the at least one distal stent. The proximal stent and the at least one distal stent each comprise an expandable stent constructed with a wire skeleton having one or more parts that extends from the proximal to the distal ends. The CSA of the proximal end of the distal stent (2) is larger than the CSA of the distal orifice of the proximal stent so as to partially secure together the stents when the distal stent is expanded within the proximal stent (col. 3, ll. 29-36).

14. Regarding claims 97 and 98, as best understood, the proximal stent of Martin can be considered to have two intermediate portions, each of which are tapered to form distal portions with distal orifices. One of these tapered portions can be considered the relatively short inclined extension that enables the distal stent to be located therein and secured thereto when the short extension has been expanded.

15. Regarding claim 99, see platinum wire (12).

16. Regarding claim 101, the proximal and distal stents are configured for placement at a bifurcation. The proximal stent includes a lumen (within 5) that is configured to be disposed

entirely within the vessel and is adapted to secure to the distal stent configured to extend into one of the two branched vessels.

17. Regarding claim 102, in figure 4 of Martin, the proximal portion of distal stent (2) and the distal portion (5) of proximal stent (1) are both tapered and cylindrical and therefore form frustoconical shapes. Martin discloses that the proximal portion of distal stent (2) fits within distal portion 5) and therefore the distal stent includes a frustoconically shaped male engaging portion and the proximal stent includes a frustoconically shaped female engaging portion. Martin further teaches that these portions form an interference fit and therefore the portions engage each other to resist longitudinal movement. Each of these portions comprises a stent made of a wire skeleton since the entire device is made from such a skeleton covered with graft material.

18. Regarding claim 103, the distal stent has a fabric layer covering its outer surface. Since the proximal end of the distal stent is placed within the distal end of the proximal stent, the fabric layer will be between the male and female portions. This will form a substantially fluid-tight seal since the male and female portions are interference fit.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. **Claim 100** is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin ‘817 in view of Liebig (US 3,805,301). Martin ‘817 discloses the invention substantially as stated above including radiographic indicia on the proximal and distal stents (wire 12). The wire of Martin ‘817 goes around the entire circumference of the stents and therefore the image of the radiopaque

markers will not vary with the rotational orientation of the stent. However, Liebig teaches that it is well known to provide markers along the longitudinal axis of a stent such that the rotational orientation affects the shape of the marker. In particular, if the graft is twisted at all, the marker will be twisted. It would have been obvious to attach the wire of Martin '817 in a longitudinal manner as taught by Liebig so that any twisting of the graft structure can be easily determined by viewing the marker. With this modification, the radiographic image of the radiographic indicia varies with rotational orientation of the stent.

21. **Claims 96-99 and 101-103** are rejected under 35 U.S.C. 103(a) as being unpatentable over Papazoglou (US 6,098,630; "Papazoglou") in view of Martin '817. Papazoglou discloses an apparatus for reinforcing a bifurcated lumen comprising a proximal stent having a proximal orifice at a proximal end and at least two transversely placed tapering portions that extend from an intermediate portion to the distal end of the proximal stent (see fig. 11, especially tapering near reference number 34). The tapering portions have a distal orifice at their ends. Papazoglou fails to disclose that the proximal stent comprises a wire skeleton and also fails to disclose at least one distal stent that is expanded within the distal orifice of the proximal stent.

22. Martin '817 teaches including a wire skeleton stent within a graft used to treat a bifurcating lumen. Furthermore, Martin '817 teaches that the proximal end of this distal stent has a larger CSA than the CSA of the orifice of the proximal stent in which it is placed to form an interference fit. It would have been obvious to one skilled in the art to have modified the device of Papazoglou to include a distal stent that fits within an orifice of the tapered portion of the proximal stent as taught by Martin '817 as well as including a wire skeleton in order to be able to reinforce the graft material itself and to be able to treat the branching vessel in the event that the aneurysm continues into the branching vessel.

23. Regarding claims 97 and 98, as best understood, Papazoglou discloses a proximal stent having two tapered portions each comprising relatively short inclined extensions with distal orifices to enable the distal stent taught by Martin ‘817 to be located therein when the short extension has been expanded.

24. Regarding claim 99, Martin ‘817 teaches radiopaque wire (12).

25. Regarding claim 101, the proximal stent includes two lumens that are capable of being disposed entirely within the main vessel if the device is moved upward as viewed in fig. 11 of Papazoglou.

26. Regarding claims 102 and 103, as discussed in more detail above, Martin '817 discloses in figure 4 that the proximal end of the distal stent and the distal end of the proximal stent may be tapered. This results in a furstoconical shape to both portions. Martin ’817 also teaches inserting the proximal end of the distal stent within the distal end of the proximal stent to form a male-female type interference fit. The distal stents are covered with a graft material. This material is interposed between the male and female engaging portions when the distal stent is inserted into the proximal stent.

27. **Claims 104 and 106** are rejected under 35 U.S.C. 103(a) as being unpatentable over Papazoglou in view of Martin ‘817 and Martin (US 5,653,743; “Martin ‘743”). Papazoglou discloses a proximal expandable stent having two transversely placed tapering portions that extend from an intermediate portion to the distal end of the proximal stent and have distal orifices at their ends. Martin '743 teaches that it is known to provide distal stents in both distal orifices of a bifurcated proximal stent (see “18” in fig. 5; col. 4, ll. 15-21 which discloses treating the internal iliac artery too, formerly known as the hypogastric artery)). Martin ‘743 further teaches that the graft may take the form of a wire skeleton covered by a graft material to provide sufficient support for the graft material. It would have been obvious to one skilled in the art to

have modified the device of Papazoglou to deploy distal stents in both tapered portions of Papazoglou in order to treat the vessel in the case where the aneurysm affects the branching vessel as well. Martin '817 teaches that it is well known to provide such a distal stent with a CSA that is larger than the CSA of the portion of the proximal stent into which it fits and is thereafter expanded within in order to form an interference fit (col. 3, ll. 29-36). It would have been obvious to one skilled in the art to have modified the device of Papazoglou to size the proximal and distal stents in this manner so that it too would have this advantage.

28. **Claim 105** is rejected under 35 U.S.C. 103(a) as being unpatentable over Papazoglou in view of Martin '817 and Martin '743, as applied to claim 104 above and further in view of Chuter (US 5,562,726). Papazoglou in view of Martin '817 and Martin '743 discloses the invention substantially but does not disclose securing the proximal and distal stents with suture. However, Chuter discloses that it is well known to use suture to attach distal graft legs to a bifurcated proximal graft (see figs. 28 and 29). It would have been obvious to one skilled in the art to have further modified Papazoglou to include securing the proximal and distal stents with suture as taught by Chuter to provide additional means of preventing the stents from separating.

Response to Arguments

29. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendment adding all new claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 6/30/2010

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
7/1/10